



4/Declaration
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of

DAVID J. BOVA

Serial No. 08/368,378

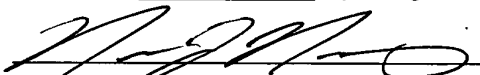
Filed January 14, 1995

For NICOTINIC ACID
COMPOSITIONS FOR TREATING
HYPERLIPIDEMIA AND RELATED
METHODS THEREFOR

) Group Art Unit 1205

) J. Venkat, Examiner

) I hereby certify that this correspondence was deposited
) with the United States Postal Service as first class mail in
) an envelope addressed to: Box NON-FEE AMENDMENT
) Assistant Commissioner, for Patents, Washington, D.C.
) 20231 on this 23rd day of August, 1995

) 
) Norma J. Nazarewicz, Sec'y to Douglas J. Hura

**DECLARATION UNDER 37 CFR §1.131 OF PRIOR INVENTION IN THE
UNITED STATES TO OVERCOME CITED PATENT**

ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

Sir:

The undersigned declares as follows:

1. He is the sole named inventor in U.S. Patent Application Serial No. 08/368,378.
2. The purpose of this Declaration is to show that the present invention was made in the United States prior to June 29, 1992, which is the filing date of U.S. Patent No. 5,268,181.
3. As evidence that the present invention was made in the United States prior to June 29, 1992, there is attached hereto as Exhibit A, relevant portions of a document entitled "A SINGLE BLIND PLACEBO CONTROLLED PILOT STUDY COMPARING THE EFFECT OF ONCE-A-DAY VERSUS TWICE-A-DAY DOSING OF SUSTAINED RELEASE NIACIN ON SERUM LIPIDS".

4. The date of Exhibit A is prior to June 29, 1992, and Actual dates and other non-relevant information has been masked from Exhibit A.

5. Exhibit A was prepared in the normal course of my employment with the Assignee of record. The experiments described therein, and hence, the reduction to practice of the present invention, were made in the United States prior to June 29, 1992.

Further Declarant sayeth not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

8/17/95

Date

David J. Bova

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CURRICULUM VITAE

Rev.10/1/95

ARTHUR RAINES

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Georgetown University
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BIRTH: May 9, 1936, New York, New York, U.S.A.

EDUCATION:

1953-1957 Fordham University College of Pharmacy, B.S. Pharmacy
1958-1960 Columbia University College of Pharmacy, M.S. Pharmacology
1960-1965 Cornell University Graduate School of Medical Sciences, Ph.D.

HONORS:

1957 Graduated with Honors from Fordham University
1984 Recipient Golden Apple Teaching Award
1956 Recipient Kaiser-Permanente Award for Excellence in Teaching
1989 Nominee, Golden Apple Award--First and Second Year Medical Classes
1992 Recipient Golden Apple Teaching Award
1994 Recipient Golden Apple Teaching Award

FELLOWSHIPS AND APPOINTMENTS:

1958-1969 Teaching Assistant, Columbia University
1960-1965 U.S.P.H.S. Predoctoral Fellow
1965-1967 U.S.P.H.S. Postdoctoral Fellow
1966-1968 Instructor, Pharmacology, Cornell University Medical College
1968-1969 Assistant Professor, Pharmacology, Cornell University Medical College and
Cornell University Graduate School of Medical Sciences
1969-1972 Assistant Professor, Pharmacology, Georgetown University, Schools of
Medicine and Dentistry
1969-1972 Lecturer, Walter Reed Army Institute for Research
1971 Supervisory Pharmacologist (Consultant), Bureau of Occupational Safety and
Health

1972-1978 Associate Professor, Pharmacology, Georgetown University, Medical, Dental and Graduate Schools
 1973-1975 Member, Advisory Committee on Neurology, Food and Drug Administration
 1977-1980 Member, Faculty Senate, Georgetown University
 1972-present Member (Ad Hoc), Several NIH Study Sections, Site Visits and Technical Merit Reviews
 1979-1982 Curriculum Committee, Dental School
 1977-1992 Member, Editorial Advisory Board, Journal of Pharmacology and Experimental Therapeutics
 1986-present Reviewer, New England Journal of Medicine
 Guest Reviewer for Journal articles: Biochemical Pharmacology, Epilepsia, Neuropharmacology, Life Sciences, Canadian Journal of Physiology and Pharmacology, Muscle-Nerve, Epilepsy Research
 1978-present Professor of Pharmacology, Georgetown University Medical, Dental and Graduate Schools
 1978-present Hospital Pharmacy Formulary (P & T) Committee (Acting Chair 5/95 - 11/95)
 1982-1985 Subcommittee for Scientific Merit Evaluation, Human Research Committee (Institutional Review Board)
 1982-1988 Committee on Corporate Interface, Patents and Conflict of Interest Chairman - 7/1/85-7/1/88
 1971-1979; 1981-1982 Consultant, Food and Drug Administration
 1983-1988 Member, Committee on Students
 1979-1980 Member, Committee for Evaluation of Anesthesiology Department
 1984-1985 Member, Committee for Evaluation of Surgery Department
 1979-1982 Course Director, Dental Pharmacology
 1983-1986 Course Director, Medical Pharmacology
 1983-present Education Committee, Medical School (Chair pre-clin. course directors 1994--)
 1983-1984 Committee on Preclinical Curriculum
 1983-1984 Committee on Academic Environment
 1984-1986 Task Force for Teaching of Geriatrics in Medicine
 1985-1986 Task Force on Instruction Evaluation
 1986-1987 Task Force for Preclinical Teacher Evaluation (Chairman)
 1984-present Member, Scientific Advisory Board, Taro Pharmaceuticals Ltd., Haifa, Israel
 1984-present Consultant, United States Pharmacopeial Convention
 1987-present Delegate, United States Pharmacopeial Convention
 1984-1986 Member, Search Committee, Neurology Chairperson
 1986-present Consultant, American Medical Association, Data Evaluation Project
 1986-1987 Task Force for Curriculum Modification and Inventory, 2nd Year Medical School (Chairman)
 1986-1988 Acting Chairman, Department of Pharmacology, Georgetown University Medical, Dental and Graduate Schools
 1987-1988 Task Force for Tuition and Class Size
 1988; 1995 Task Force LCME evaluation--faculty(1988) Curriculum (1995)
 1988 Task Force (Chairman) Medical School Drug Abuse Policy Formulation

- 1988 Task Force--Selection Kaiser Permanente Award
- 1988-present Department Committee on Faculty Recruitment
- 1989-present Department Committee on Adjunct and Secondary Appointments (Chair)
- 1989-1990 Vice Chairman, Medical Center Committee on Scientific Fraud and Misconduct
- 1989-1991 Course Director: Fundamentals of Pharmacology
- 1989-1990 Member, Search Committee--Chair in Emergency Medicine
- 1989-1990 Member, Committee for the Evaluation of the Department of Physiology
- 1990-present Professor of Neurology
- 1990-present University Committee on Scientific Misconduct (1990-94, Chairman)
- 1991-present Medical Center Committee on Conflict of Interest
- 1990-1991 Course Director: Neurology & Neurosurgery Resident course in Advanced Concepts in Neuropharmacology
- 1991-present Course Director: Medical Pharmacology
- 1991-present Consultant (Pharmacology/Toxicology): Stedman's Medical Dictionary; Williams & Wilkins Publishers
- 1992-present Member, Library Committee; Georgetown University Medical Center
- 1993-present Member, Problem Based Learning Planning Committee.
- 1993-1995 President, Sigma Xi Research Society, Georgetown University Chapter
- 1995-present Secretary, Sigma Xi Research Society, Georgetown University Chapter
- 1995-present President, Amer. Assoc. Univ. Prof. Georgetown University Chapter

1995-present Member, Problem Based Learning Evaluation Committee

PROFESSIONAL SOCIETIES; ELECTED TO MEMBERSHIP:

- American Society for Pharmacology and Experimental Therapeutics
- Rho Chi Society
- Sigma Xi
- A.A.A.S.
- New York Academy of Sciences
- Society for Experimental Biology and Medicine
- American Epilepsy Society
- Society for Neuroscience
- Drug Information Association
- International Brain Research Organization
- American Chemical Society
- American Assn. of University Professors
- American College of Clinical Pharmacology (Chesapeake Chptr.)

GRANTS AND AWARDS:

- 3/67-6/69 Factors influencing the capacity of digitalis to induce cardiac rhythm disorders.
New York heart Association [\$30,000]
- 1971-1974 Neuropharmacology of the heart. U.S.P.H.S. [\$95,000]
- 1971-1974 Pharmacology of nerve terminals. U.S.P.H.S. [\$105,000]
- 1/70-12/70 Effects of digitalis on spinal cord function. Washington Heart Association.
[\$7500]
- 6/2-6/73 Anticonvulsant effects of diphenylbarbituric acid. NINDS. [\$5000]
- 3/74-3/76 Effects of anticonvulsant drugs on cerebellar function. U.S.P.H.S. [\$79,300]
- 4/76-8/80 Effects of anticonvulsant drugs on cerebellar function. Competitive Renewal.
U.S.P.H.S. [\$96,744]
- 7/76-6/80 Effects of drugs on motor systems. U.S.P.H.S. [\$163,452]
- 10/82-9/85 Standardized model for spinal cord injury. NINCDS. [\$44,000--part of
Program Project]
- 3/83 Anticonvulsant drug development program. International Biological Research
Corporation. [indefinite period, \$3,300]
- 3/88-3/91 Influence of sublethal exposure to Soman on neurologic cardiovascular,
respiratory and enzymatic function. U.S. Army Research and
Development Command. [\$424,400] Co-principal Investigator
- 7/95 Development of novel anticonvulsant and muscle relaxant compounds : with
Darryl Abernethy, M.D. Ph.D. Taro Pharmaceuticals \$ 12,500 indefinite
period.

INVITED PRESENTATIONS, SEMINARS AND SYMPOSIA

<u>DATE</u>	<u>TITLE</u>	<u>HOST AND PLACE</u>
May 1968	The influence of anticonvulsant drugs on motor nerve terminals	Epilepsy Branch, NIH, Salt Lake City, UT
Nov. 1968	The nervous system as a site of action for antiarrhythmic and antiarrhythmogenic drugs	Cardiovascular Research Lab., NIH, Bethesda, MD
Dec. 1968	The influence of diphenylhydantoin on neuromuscular function	Pharmacology Dept., Univ. of Texas Sch. of Med., Galveston, TX
June, 1969	Stabilization of motor nerve endings by diphenylhydantoin	Neurology Dept., Cornell Univ. Sch. of Medicine, New York, NY
March, 1972	The neuropharmacology of anti-epileptic drugs	Pharmacology Dept., Med. Col. of Pennsylvania, Philadelphia, PA
Sept. 1972	Neural control of cardiac function: implications for antiarrhythmic drug actions	Dept. of Pharmacology, Howard Univ. Med. School, Washington, DC
Feb. 1973	Anticonvulsant properties of diphenylbarbituric acid in the mouse	Epilepsy Branch, NIH, Bethesda, MD
Feb. 1976	The influence of phenytoin on sensorimotor function and its relation to treatment in spasticity	Neurology Dept., Cornell Univ. Sch. of Medicine, New York, NY
March, 1976	The use of phenytoin and chlorpromazine in the treatment of spasticity	Neurology Department, Mt. Sinai School of Med., New York, NY
May, 1976	Novel pharmacologic approaches in the treatment of spasticity	Burke Rehabilitation Center, Cornell Med. College, Westchester, NY
May, 1977	Phenytoin Revisited; Symposium Presentation	Pharmacology Dept., Georgetown Univ., Med. Sch., Washington, DC

June, 1977	The influence of phenytoin on experimental hypertonus in the cat; implications for treatment of spasticity	Physiol. & Pharmacol. Dept., Duke Univ. Sch. of Med., Durham, NC
June, 1977	The use of dilantin, with and without thorazine in humans with spasticity	Parke-Davis & Company, Ann Arbor, MI
Dec. 1977	The pharmacologic management of spasticity	Rehabilitation & Physical Therapy Dept., Suburban Hosp., Bethesda, MD
March 1978	The influence of phenytoin on the muscle spindle and its relation to hypertonus in man	Neurology Dept., Cornell Univ. Sch. of Med., New York, NY
Nov. 1978	The actions of phenytoin and chlorpromazine in motor function in cats and humans	Pharmacology Dept., Univ. of West Virginia Sch. of Med., Morgantown, WV
Dec. 1978	Phenytoin's actions on somato-sensory systems	Pharmacology Dept., Cornell Univ. Sch. of Med., New York, NY
Aug. 1979	Effects of anticonvulsants on motor function: implications for mechanisms of action, drug intoxication, anticonvulsant screening procedures and new therapies in spasticity	NIH & ASPET, Portland, OR
Dec. 1979	Pharmacokinetics of anticonvulsant drugs in man with specific reference to toxicity	Neurology Dept., Children's Hosp., Washington, DC
Jan. 1980	Phenytoin as a muscle relaxant in hypertonic disorders	Warner-Lambert Corp., Morris Plains, NJ
June, 1980	New approaches in muscle spasticity	Univ. of Michigan and Warner-Lambert Corp., Ann Arbor, MI
Oct. 1980	Phenytoin action on nerve and muscle	Neurology Dept., Georgetown Univ. Hosp., Washington, DC

May, 1981	The muscle spindle as a target for the actions of phenytoin	Pharmacology Dept., Howard Univ., Washington, DC
Oct. 1981	The effects of phenytoin on sensory and motor systems in the cat	Pharmacology Dept., Univ. of Pennsylvania Col. of Med., Hershey, PA
June, 1984	The effects of phenytoin and chlorpromazine to produce hypotonia in the cat and man	A.H. Robins Pharmaceuticals, Richmond, VA
Aug. 1984	Efficacy of phenytoin and calcium antagonists on organophosphate poisoning	U.S. Army, Chemical & Biological Defense Division, Aberdeen, MD
Oct. 1984	Experimental preclinical and clinical studies on muscle hypertonus of central nervous system origin	Veterans Administration Hosp., Washington, DC
April 1985	Update on the use of newer analgesic agents	Dental Study Group of the Washington Metropolitan Area, Washington, DC
April 1985	Muscle relaxant properties of phenytoin in the cat and man	Dept. of Neurology, Univ. of Indiana Sch. of Med., Indianapolis, IN
April 1985	The role of phenytoin and calcium blockers in organophosphate poisoning	Dept. of Pharmacology, Univ of Indiana Sch. of Med., Indianapolis, IN
Feb. 1986	Phenytoin and calcium blockers prevent organophosphate toxicity and enhance protection by atropine and 2-PAM	A.H. Robins Pharmaceuticals, Richmond, VA
May 1986	Pharmacokinetic principles: uptake and distribution of anesthetic drugs and adjuncts to anesthesia	Dept. of Anesthesiology, The Fairfax Hospital, Fairfax, VA
Nov. 1988	Pharmacologic bases for muscle relaxation; relationships to motor systems	Sterling-Winthrop Research Institute, Rensselaer, NY

Mar. 1989	Pharmacokinetic factors in determining serum levels of antiepileptic drugs	Dept. of Neurology, Georgetown Univ. Hosp., Washington, DC
May 1989	Pharmacokinetic factors in drug distribution	Dept. of Neonatology, Columbia Hosp. for Women, Washington, DC
June 1990	Protective effects of phenytoin and calcium blockers on organophosphate induced toxicity	Dept. of Pharmacology, Georgetown University Med. Sch., Washington, DC
Mar. 1991	The pharmacology of anxiety	Pharmaceutical Manufacturers Association, Advanced Course
Apr. 1991	Effects of phenytoin and calcium blockers on fasciculations and toxicity produced by anticholinesterase drugs	Dept. of Neurology, Georgetown Univ. Med. Ctr., Washington, DC
Apr. 1995	Anticonvulsant Barbiturates: New Fruit from an Old Tree	Div. Clinical Pharmacology; Georgetown University Med. Ctr.
Nov. 1995	Drug Development of New Anti- convulsant Barbiturates	Dept. of Neurology, Veterans Admin. Hosp. Washington, D.C.

BIBLIOGRAPHY
ARTHUR RAINES

PUBLICATIONS:

- Raines, A.: The influence of stress on adrenocortical function in the rat. Masters Dissertation. Columbia University, 1960.
- Raines, A.: Effects of diphenylhydantoin on post-tetanic alterations in the terminals of dorsal root fibers and motor nerves. Ph.D. Dissertation. Cornell University, 1965.
- Raines, A. and F.G. Standaert: Pre- and post-junctional effects of diphenylhydantoin at the cat soleus neuromuscular junction. *J. Pharmacol.*, 153: 361-366. 1966.
- Raines, A. and F.G. Standaert: An effect of diphenylhydantoin on post-tetanic hyperpolarization of intramedullary nerve terminals. *J. Pharmacol.*, 156: 591-597, 1967.
- Raines, A., B. Levitt and F.G. Standaert: The effect of spinal section on ventricular rhythm disorders induced by ouabain. *Arch. Internat. de Pharmacodyn. et de Therap.* 170: 485-490, 1967.
- Raines, A. and B. Levitt: The failure of diphenylhydantoin to influence the beta-adrenergic receptor of the heart. *Arch. Internat. de Pharmacodyn. et de Therap.* 172: 432-441, 1968.
- Raines, A., D. Moros and B. Levitt: The effect of guanethidine on ouabain-induced ventricular arrhythmia in the cat. *Arch. Internat. de Pharmacodyn. et de Therap.* 174: 373-377, 1968.
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- Raines, A.: Effects of tetanization on transmitter dynamics (Discussion). *Epilepsia* 10: 206-209, 1969.
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- Sohn, Y.J., A. Raines, F.G. Standaert and B. Levitt: The effect of diphenylthiohydantoin on digitalis-induced cardiac arrhythmia. *Arch. Internat. de Pharmacodyn. et de Therap.* 179: 434-441, 1969.
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